K032569

SEP 1 6 2003

EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. **Submitter's Identification:**

   Rex Medical
   555 North Lane, Suite 6101
   Conshohocken, PA 19428

   Date Summary Prepared: August 19, 2003

   Contact:

   Mr. Michael Paris
   Catheter Engineer

2. **Name of the Device:**

   Short Introducer Sheaths

3. **Predicate Device Information:**

   K#022170, Rex Medical Inner-Lock Locking Introducer Sheath, Rex Medical

4. **Device Description:**

   The Rex Medical Short Introducer Sheaths, offered in both 6F and 7F sizes, are vascular access devices consisting of a central lumen, angled side arm extension, and a hemostasis valve. The device is used under identical indications for use as the predicate device, as well other substantially equivalent 510(K) cleared devices.

5. **Intended Use:**

   The Short Introducer Sheaths are used to facilitate placing a catheter through the skin into a graft. The dilator is an accessory device which is used by placing it into the sheaths to create an occlusion and further provide support to the wall of the indwelling system.

6. **Comparison to Predicate Devices:**

Discussion of Similarities:

The Rex Medical Short Introducer Sheaths are identical to the Rex Medical Inner-Lock Locking Introducer Sheaths as follows: Both devices make use of a dilator with a central lumen to pass over a guidewire during insertion; both devices incorporate the same integrated hemostasis valve, extension tube, clamp, female luer, and proximal cap. Both devices are indicated for dialysis graft access.

Discussion of Differences:

The Short Introducer Sheaths differ from the Inner-Lock Locking Introducer Sheaths by means that the retention feature has been eliminated for the short introducer sheath design. When eliminating the retention feature, the coaxial sheath tubing design, which is required to create the retention feature in the Inner-Lock, is no longer necessary so a less complicated single sheath lumen design was incorporated. The combined wall thickness for the Inner-Lock Sheath Coaxial Tubing is 0.012" (each tubing has a specified wall thickness of .006") and the Short Introducer sheath single lumen design has a wall thickness of 0.010". The usable sheath length for the Short Introducer Sheath design will be 5cm as opposed to the 4cm specified length of the Inner-Lock. The bore ID of the hub is specified as .110" for the Inner-Lock and will be increased to 0.118" for the Short Introducer Sheath. The distal cap used to manufacture the Inner-Lock sheath introducer provided a cut-out section for the rotator knob which is used to activate the retention feature. The Short Introducer Sheath does not require a rotator knob so the distal cap will not provide the cut-out section.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

All testing performed on the Short Introducer Sheath were derived from the risk assessment which evaluated the slight deviation in design from the Inner-Lock Sheath Introducer. Test methodology and acceptance criteria were derived form ISO 11070, Sterile single-use intravascular catheter introducers. All materials used in the Short Introducer Sheath are identical to the Inner-Lock Locking Introducer Sheath with the exception that a color additive was added to the base extrusion. All materials used in the Inner-Lock Locking Introducer Sheath were tested according to ISO 10993-1, Biological Evaluation of Medical Devices.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. Conclusions:

The subject device, Short Introducer Sheath, has identical indications use as the Rex Medical Inner-Lock Introducer Sheath. The bench testing contained in our submission demonstrates that there are no differences in their technological characteristics, thereby not raising any new question of safety or effectiveness. Thus, the Short Introducer Sheath is substantially equivalent to the Rex Medical Inner-Lock Introducer Sheath.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 6 2003

Rex Medical
c/o Ms. Susan D. Goldstein-Falk
mdi Consultants
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K032569
Trade Name: Short Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: August 19, 2003
Received: August 20, 2003

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

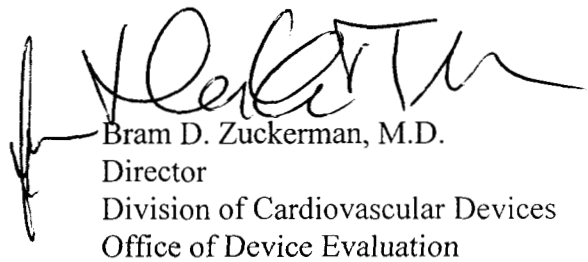
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K032569

Device Name: Rex Medical Short Introducer Sheaths

Indications For Use:

The Short Introducer Sheaths are used to facilitate placing a catheter through the skin into a graft. The dilator is an accessory device which is used by placing it into the sheaths to create an occlusion and further provide support to the wall of the indwelling system.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use_____
(Optional ~~F~~ormat 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032569